Remarks

Requirement for Restriction

The Restriction Requirement divides the claims into two groups:

I. Claims 1, 3-5, 8-10, 15, 18-21, 23-25, 27, 28 and 37-40 as drawn to a method of treating or ameliorating a respiratory infection or a symptom thereof, in a human subject suffering therefrom, said method comprising [sic] an antagonist or an antibody or fragment thereof comprising a VH CDR1 comprising the amino acid sequence of SEQ ID NO:26, a VH CDR2 comprising the amino acid sequence of SEQ ID NO:64, a VH CDR3 comprising the amino acid sequence of SEQ ID NO:3, a VL CDR1 comprising the amino acid sequence of SEQ ID NO:65, a VL CDR2 comprising the amino acid sequence of SEQ ID NO:66, and a VL CDR3 comprising the amino acid sequence of SEQ ID NO:20; and

II. Claims 1, 3-5, 8-10, 15, 18-21, 23-25, 27, 28 and 37-40 as drawn to a method of treating or ameliorating a respiratory infection or a symptom thereof, in a human subject suffering therefrom, said method comprising [sic] an antagonist or an antibody or fragment thereof comprising a VH domain comprising the amino acid sequence of SEQ ID NO:27 and a VL domain comprising the amino acid sequence of SEQ ID NO:28.

See Restriction Requirement at the paragraph bridging pages 2 and 3. As an initial matter, Applicant wishes to clarify the subject matter encompassed by the claims in Groups I and II.

The independent claims of Groups I and II, claims 1, 3, 4, and 5, are not solely directed to methods of treating, or ameliorating a respiratory infection or a symptom thereof, as indicated in the Restriction Requirement. Claim 1 is directed to a method of managing, treating, or ameliorating a respiratory infection, or a symptom thereof. Claim 3 is directed to a method of preventing, managing, treating, or ameliorating wheezing in a human preterm infant a human infant or a human child. Claim 4 is directed to a method of preventing, managing, treating or ameliorating wheezing in a human subject suffering therefrom. Claim 5 is directed to a method of preventing, managing, treating or ameliorating asthma or an allergy, or one or more symptoms thereof.

Furthermore, claim 1 does not recite a step of administering an antagonist comprising a VH CDR1, VH CDR2, VH CDR3, VL CDR1, VL CDR2, and VL CDR3 as the Restriction Requirement indicates for the Group I claims. It also does not recite administering an antagonist comprising a VH and a VL domain as the Restriction Requirement indicates for the Group II claims. Claim 1 comprises a step of "administering to said human subject an effective amount of an IL-9 antagonist."

Traversal of Requirement for Restriction

The Manual of Patent Examining Procedure (M.P.E.P) § 803 (I) sets forth two criteria for restriction between patentably distinct inventions which include:

(A) The inventions must be independent or distinct; ***and***

(B) There would be a serious burden on the examiner if restriction is not required. M.P.E.P § 803 (I) (emphasis added).

Applicants respectfully submit that the subject matter of Groups I and II should not be restricted because a search of these two groups would be co-extensive and therefore would not impose a serious burden on the Patent Office.

The claims designated as being in Groups I and II, as restricted by the Patent Office, are *identical*. The Restriction Requirement points out a single distinguishing feature between the Group I and II claims: the antagonist or antibody or antibody fragment (hereinafter "agent") administered in the methods. The Restriction Requirement designates the claims as being in Group I if the agent comprises a VH CDR1, VH CDR2, and VH CDR3 as shown in SEQ ID NOs:26, 64, and 3, respectively and a VL CDR1, VL CDR2, and VL CDR3 as shown in SEQ ID NOs: 65, 66 and 20, respectively. The Restriction Requirement designates the claims as being in Group II if the agent comprises a VH and a VL domain comprising the amino acid sequences of SEQ ID NOs:27 and 28, respectively. See Restriction Requirement at pages 2-3, quoted above.

Applicant respectfully submits that any search for methods which comprise administering an agent as recited according to the Group I designation (VH CDRs 1, 2, and 3 comprising the amino acid sequences of SEQ ID NOs: 26, 64, and 3, respectively, and VL CDRs 1, 2, and 3 comprising the amino acid sequences of SEQ ID NOs: 65, 66, and 20, respectively), will ***necessarily*** produce search results relevant to the same methods comprising administering an agent as recited according to the Group II designation (VH and VL domains comprising amino acid sequences as shown in SEQ ID NOs:27 and 28, respectively). See the specification at ¶ 144 and Figure 8. Specification paragraph 144 discloses that a Group II VH domain[1] (SEQ ID NO:27) comprises Group I VH CDRs 1, 2, and 3 (amino acid sequences comprising SEQ ID NOs:26, 64, and 3); and a Group II VL domain (SEQ ID NO:28) comprises Group I VL CDRs 1, 2, and 3 (amino acid sequences comprising SEQ ID NOs:65, 66, and 20). Thus, an agent comprising Group II VH and VL

[1] For the sake of brevity, Applicant will refer to the Group I and II "inventions" by their distinguishing feature as alleged in the Restriction Requirement, *i.e.*, agent comprising recited VH and VL domains or comprising recited VH and VL CDRs.

domain amino acid sequences (SEQ ID NOs:27 and 28) comprises the Group I VH and VL CDR amino acid sequences (SEQ ID NOs:26, 64, 3, 65, 66, and 20). Because an agent comprising the Group II VH and VL domain amino acid sequences comprises the Group I VH and VL CDR amino acid sequences, a search of the claims as designated in Group I will necessarily produce relevant search results to the claims as designated in Group II, *i.e.*, a search of the claims as designated in Group I or II is co-extensive with the other. Such a co-extensive search will not impose a serious burden on the Patent Office.

Furthermore, the claims designated as being in Groups I and II have not acquired a separate status in the art. The claims in both Groups I and II are classified in class 514, subclass 44. This identical classification supports Applicant's position that co-examination of these Groups would not impose a serious burden on the Patent Office.

Election

To fully comply with the Restriction Requirement, Applicant elects the claims designated in Group I. Applicant further elects the following species for examination: viral infection as the respiratory infection, bronchopulmonary dysplasia as the respiratory disease, and anti-viral agent as the additional therapy. Claims 1, 3, 4, 8-10, 15, 20, 23-25, 27, 28 and 37-40 read on the elected species of the currently pending Restriction Requirement in combination with the Restriction Requirement dated September 22, 2006.

Respectfully submitted,

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Michelle Holmes-Son (47,660)
MedImmune, Inc.
One MedImmune Way
Gaithersburg, MD 20878
Telephone: 301-398-5765